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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/899,432	07/06/2001	Robert Kleiman	511-051	3374

7590 01/13/2004

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EXAMINER	
JIANG, SHAOJIA A	
ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 01/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/899,432	KLEIMAN ET AL.	
	Examiner	Art Unit	
	Shaojia A Jiang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 October 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) *See Continuation Sheet* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-3, 5-6, 8-9, 11-12, 14-15, 17-18, 20-21, 23-24, 26-27, 29-30, 32-33, 35-36, 86-87, and 89-90* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Continuation of Disposition of Claims: Claims pending in the application are
2,3,5,6,8,9,11,12,14,15,17,18,20,21,23,24,26,27,29,30,32,33,35,36,38,39,41,42,44,45,47,48,50,51,53,54,56,57,59,60,62,63 65,66,68,69,71,72,74,75,77,78,80,81,83,84,86,87,89 and 90.

Continuation of Disposition of Claims: Claims withdrawn from consideration are
38,39,41,42,44,45,47,48,50,51,53,54,56,57,59,60,62,63,65,66,68,69,71,72,74,75,77,78,80,81,83 and 84.

DETAILED ACTION

This Office Action is a response to Applicant's amendment and response filed on October 27, 2003 wherein the instant specification has been amended as to page 12, the last paragraph; claims 2-3, 5-6, 8-9, 11-12, 14-15, 17-18, 20-21, 23-24, 26-27, 29-30, 32-33, 35-36, 86-87, and 89-90 have been amended. It is noted that claims 1, 4, 7, 10, 13, 16, 19, 22, 25, 28, 31, 34, 37, 40, 43, 46, 49, 52, 55, 58, 61, 64, 67, 70, 73, 76, 79, 82, 85, and 88 have been cancelled previously and Claims 38-39, 41-42, 44-45, 47-48, 50-51, 53-54, 56-57, 59-60, 62-63, 65-66, 68-69, 71-72, 74-75, 77-78, 80-81, and 83-84 drawn to an invention nonelected with traverse (see the previous Office Action May 20, 2003).

Currently, claims 2-3, 5-6, 8-9, 11-12, 14-15, 17-18, 20-21, 23-24, 26-27, 29-30, 32-33, 35-36, 38-39, 41-42, 44-45, 47-48, 50-51, 53-54, 56-57, 59-60, 62-63, 65-66, 68-69, 71-72, 74-75, 77-78, 80-81, 83-84, 86-87, and 89-90 are pending in this application.

Claims 2-3, 5-6, 8-9, 11-12, 14-15, 17-18, 20-21, 23-24, 26-27, 29-30, 32-33, 35-36, 86-87, and 89-90 as amended now are examined on the merits herein.

Applicant's amendment (amended claims 14-15, 17-18 and 20-21, 23-24) and remarks filed October 27, 2003 with respect to the objection to these claims for being duplicated of one another, and for minor informalities, i.e., "of", is missing, of record stated in the Office Action dated May 20, 2003 have been fully considered and found persuasive. Therefore, this said objection is withdrawn.

Applicant's amendment (amended claims 2-3, 5-6, 8-9, 11-12, 14-15, 17-18, 20-21, 23-24, 26-27, 29-30, 32-33, 35-36, 86-87, and 89-90) and remarks filed on October 27, 2003 with respect to the rejection of these claims made under 35 U.S.C. 112 second paragraph for the use of the indefinite expressions, i.e., "from 0.1 to 25 percent by weight", "preferably.." and "mammal suspected..." of record stated in the Office Action dated May 20, 2003 have been fully considered and found persuasive to remove the rejection since these expressions have been removed from the claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-6, 11-12, 17-18, 23-24, 29-30, 35-36 and 89-90 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, of record in the Office Action dated May 20, 2003.

Applicant's remarks regarding the term "relative" in claims 5-6, 11-12, 17-18, 23-24, 29-30, 35-36 and 89-90 have been fully considered. However, the claims are still not clear as to whether the "relative proportions of octodecenol of about 1%, eicosenol of about 44%, docosenol of about 45%, and tetracosenol of about 9% is by weight, by volume, or by mol, or a ratio. Moreover, the independent claim 2 recites that the concentration of one of more these monounsaturated alcohols is from 0.1 to 25% by weight, whereas the dependent claim 5 for example recites "eicosenol of about 44%,

docosenol of about 45%", whose concentration is higher 25%. Thus, the recitation in dependent claim 5 is improper.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2-3, 5-6, 8-9, 11-12, 14-15, 17-18, 20-21, 23-24, 26-27, 29-30, 32-33, 35-36, 86-87, and 89-90 as amended now are rejected under 35 U.S.C. 103(a) as being unpatentable over Katz et al. (5,952,392) in view of ARQUETTE et al. (WO 9920224) and Katz (4,874,794) and Katz (5,070,107) for the same reasons of record stated in the Office Action dated May 20, 2003.

Katz et al. (5,952,392) discloses that long chain fatty acids broadly including oleic acid (C18, one double bond, see col.2 lines 12-15; col. line 5-8, col.4 line 26-28) or monounsaturated long chain alcohols broadly (e.g., C18-C28, or octadecenol and docosenol) in their effective amounts with a physiologically compatible carrier (e.g., cream or ointment applied to skin, or aqueous solution, see Example 12, 14-15 at col.20 line 34-35 and col.22 line 39-40 and 64) are useful in a pharmaceutical composition for topical application and intramuscular and intravenous injections, and methods of treating viral infections and virus-induced and inflammatory disease of skin and

membranes because these compounds have antiviral activity. See abstract, col.1 lines 10-15 and 20-47; col.3 lines 18-21; Examples 14-15 at col.22-23. Katz et al. also discloses that the effective amount of docosenol in the pharmaceutical composition is about 10% to 12% w/w (by weight, within the instant claim, see col.6 line 64, col.16 lines 59-60 and claims 10-11).

The prior art does not expressly disclose the employment of monounsaturated long chain alcohols in combination with long chain fatty acids salts herein in a pharmaceutical composition, which may further comprising the fatty acid esters herein, in a method for treating virus-induced and inflammatory disease of skin and membranes.

Arquette et al. (WO 9920224) discloses a pharmaceutical composition comprising the instant fatty alcohols at least 10% by weight (see particularly abstract and page 3 lines 15-22), jojoba oil (known to contain the instant fatty acids, see page 4 entirely), and the instant fatty acid esters in their various percentages (see page 4-8) with a physiologically compatible carrier for topical applications (see abstract and claims 1-12

Katz et al. (4,874,794) discloses that the effective amounts of long chain fatty alcohols broadly (e.g., C20-C26) with a physiologically compatible carrier in a pharmaceutical composition for topical application for methods of treating viral infections and skin inflammations are 0.1 to 25 percent by weight. See abstract, col.3 lines 63-68, claims 1-2.

Katz et al. (5,070,107) discloses that the effective amounts of long chain fatty alcohols broadly (e.g., C27-C32) with a physiologically compatible carrier in a pharmaceutical composition for topical application and intramuscular and intravenous injections for methods of treating viral infections and skin inflammations are 0.1 mg to 2 g/per 50kg of body weight. See abstract, col.3 lines 63-68, claims 1-2.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ the instant monounsaturated long chain alcohols in combination with the instant fatty acids salts herein in a pharmaceutical composition, which may further comprising the instant fatty acid esters herein, in methods for treating virus-induced and inflammatory disease of skin and membranes, and to optimize the effective amounts of active agents in the composition herein to be administered.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ the instant monounsaturated long chain alcohols in combination with the instant fatty acids salts herein in a pharmaceutical composition, which may further comprising the instant fatty acid esters herein, in methods for treating virus-induced and inflammatory disease of skin and membranes since long chain fatty acids broadly or monounsaturated long chain alcohols broadly in their effective amounts with a physiologically compatible carrier are known to be useful in pharmaceutical compositions for topical application and intramuscular and intravenous injections, for methods of treating viral infections and virus-induced and inflammatory disease of skin and membranes because these compounds have antiviral activity based on Katz et al. Moreover, the instant fatty alcohols at least 10% by weight, or about 10% to 12% w/w

by weight of docosenol in the pharmaceutical composition disclosed by Katz et al. (5,952,392), or 0.1 mg to 2 g/per 50kg of body weight also disclosed by Katz et al. (5,070,107 and 4,874,794), the instant fatty acids, and the instant fatty acid esters in their various percentages with a physiologically compatible carrier are known to be useful in a pharmaceutical composition for topical applications according to Arquette et al.

Therefore, one of ordinary skill in the art would have reasonably expected that combining the instant fatty alcohols, the instant fatty acids, and the instant fatty acid esters taught in Arquette et al. in a pharmaceutical composition to would improve the therapeutic effect for treating virus-induced and inflammatory disease of skin and membranes since these components are known to be useful in treating virus-induced and inflammatory disease of skin and membranes.

Since all active composition components herein are known to useful to treat virus-induced and inflammatory disease of skin and membranes, it is considered prima facie obvious to combine them into a single composition to form a third composition useful for the very same purpose. At least additive therapeutic effects would have been reasonably expected. See *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980).

Additionally, one of ordinary skill in the art would have been motivated to optimize the effective amounts of active ingredients in the composition because the optimization of known effective amounts of known active agents to be administered according the disclosures of Katz et al. and Arquette et al., is considered well within the skill of artisan. It has been held that it is within the skill in the art to select optimal

parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

Applicant's remarks filed on October 27, 2003 with respect to this rejection of made under 35 U.S.C. 103(a) of record in the previous Office Action dated May 20, 2003 have been fully considered but are not deemed persuasive as to the nonobviousness of the claimed invention over the prior art. These remarks are believed to be adequately addressed by the obvious rejection presented above.

Additionally, contrary to Applicant's assertion that Katz '392 does not disclose the specific physiologically compatible carrier, Katz '392 clearly discloses that a physiologically compatible carrier in a form e.g., cream or ointment applied to skin, or aqueous solution, as discussed above. Moreover, the instant claims merely recite "a physiologically compatible carrier".

Further, Applicant's arguments that none of Katz references ('392, '794, or '107) teach or disclose the medical effects of the instant salts of fatty acids or mixed esters, are not found convincing. As discussed above, fatty acids and their esters are known to be in a pharmaceutical composition for topical application and intramuscular and intravenous injections, and methods of treating viral infections and virus-induced and inflammatory disease of skin and membranes. It has been well-settled that the non-toxic salts of the compound, i.e., the non-toxic salts of fatty acids to be employed in the same treatment as fatty acids, would be considered to be obvious, since one of ordinary skill

in the art would recognize that the non-toxic salts of fatty acids and fatty acids would have same or substantially similar activities as anti-viral agents (see MPEP 2143.02).

Applicant's testing data in the specification at pages 23-26 have been fully considered with respect to the nonobviousness and/or unexpected results of the claimed invention over the prior art and but are not deemed persuasive. The results on the tests of the employment of the tested composition within the instant claim in vitro in the specification have been fully considered but are not deemed persuasive as to unexpected results over the prior art for reasons discussed below. The results on test on the composition herein, demonstrate that the composition herein has anti-viral effects, as taught and suggested by the cited prior art herein. Therefore, the results herein are clearly expected and not unexpected based on the cited prior art. Expected beneficial results are evidence of obviousness. See MPEP § 716.02(c). In this regard, it is noted that the specification provides no side-by-side comparison with the closest prior art in support of nonobviousness for the instant claimed invention over the prior art.

Therefore, the evidence presented in Examples herein is not seen to support the nonobviousness of the instant claimed invention over the prior art.

For the above stated reasons, said claims are properly rejected under 35 U.S.C. 103(a). Therefore, said rejection is adhered to.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

S. Anna Jiang, Ph.D.
Patent Examiner, AU 1617
January 2, 2004

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER

1/12/04